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# Sizing Strategy and PVL Management: Most Experienced Strategy

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# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## **Affiliation/Financial Relationship**

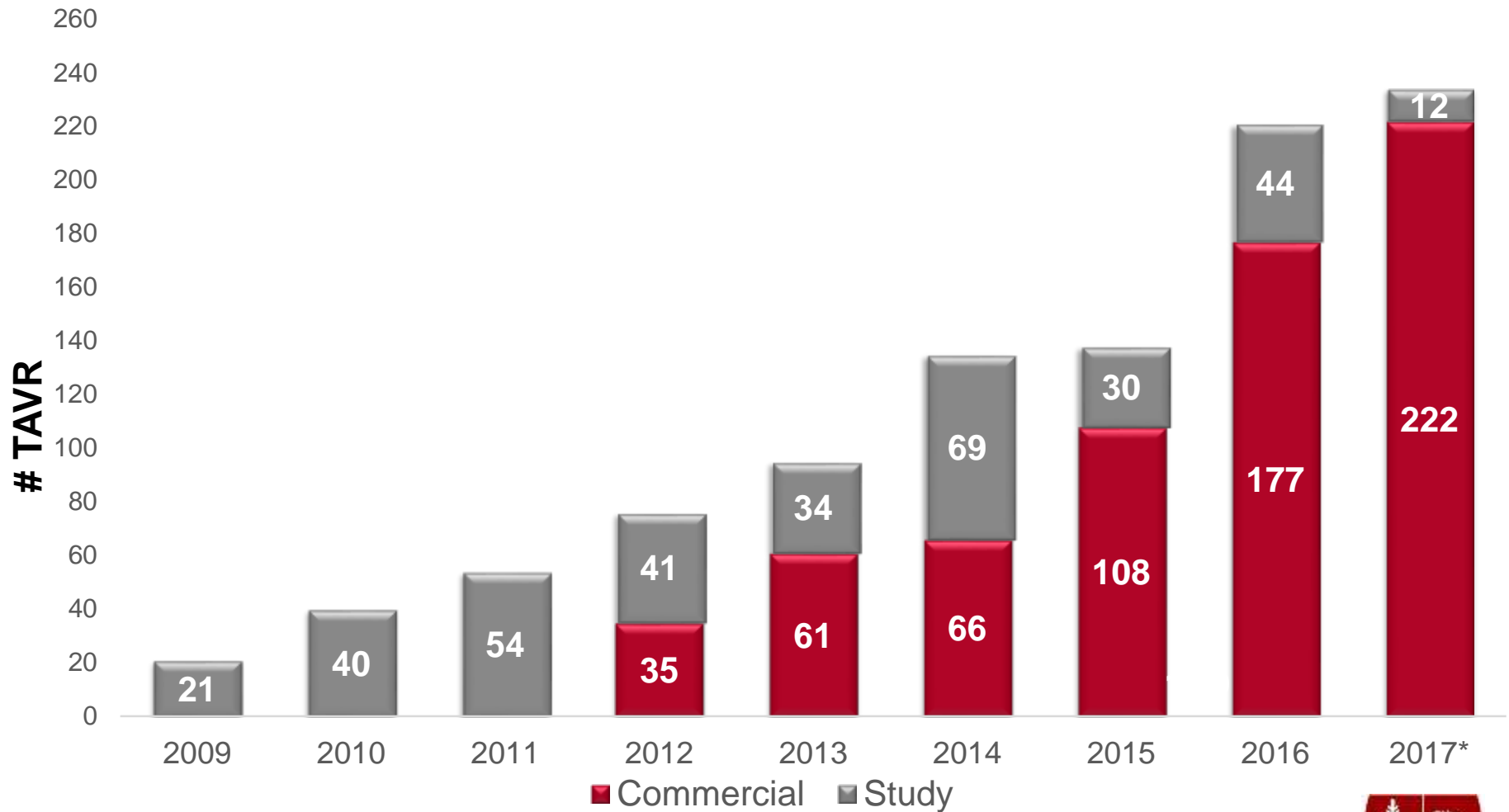
- Grant/Research Support
- Grant/Scientific Advisory Board
- Executive Physician Council

## **Company**

- Edwards Lifesciences
- Medtronic
- Boston Scientific Corp



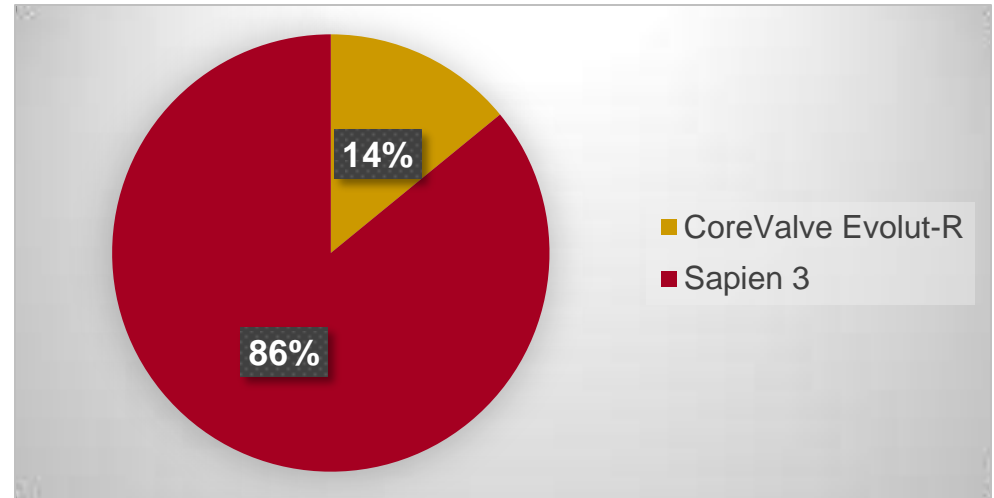
# Stanford Experience with TAVR





# In the past 3 months...

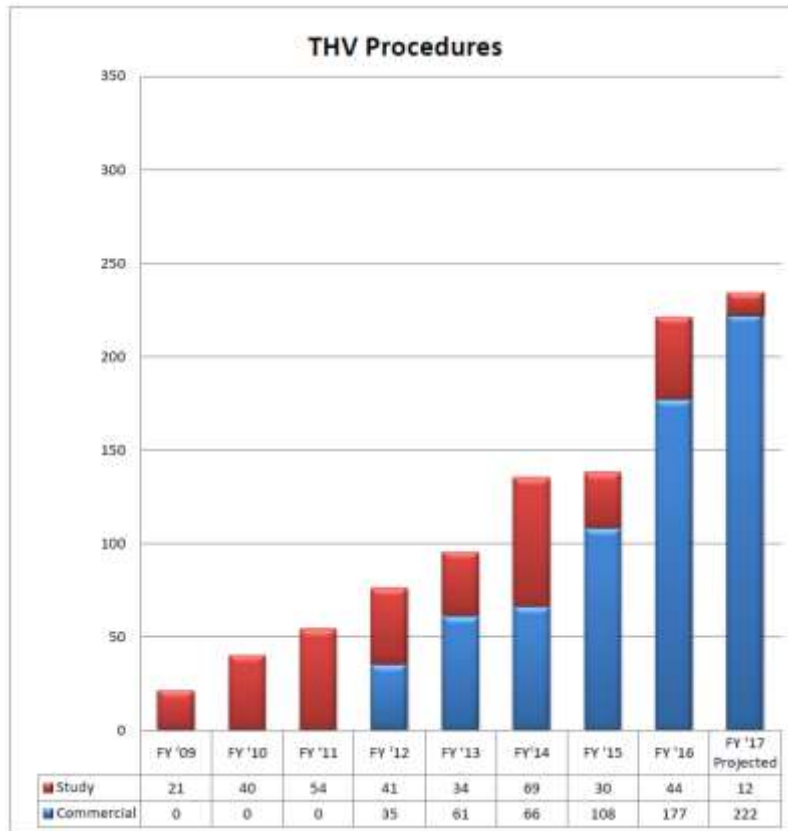
| Valve              | # of Cases |
|--------------------|------------|
| Sapien 3           | 61         |
| CoreValve Evolut R | 10         |



| Complications | n (71) |
|---------------|--------|
| PPM/ ICD      | 7%     |
| Death (TA)    | 1%     |
| Major Vasc    | 3%     |
| Stroke        | 0%     |



# In the past 3 months...



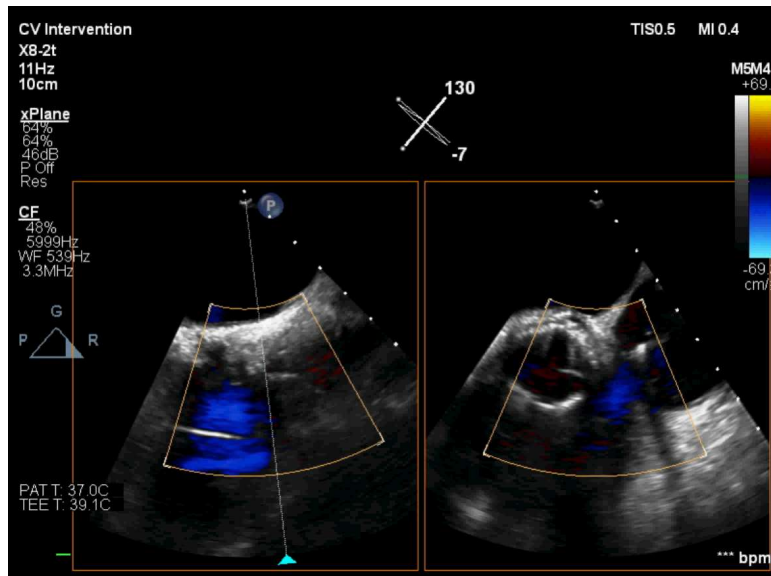
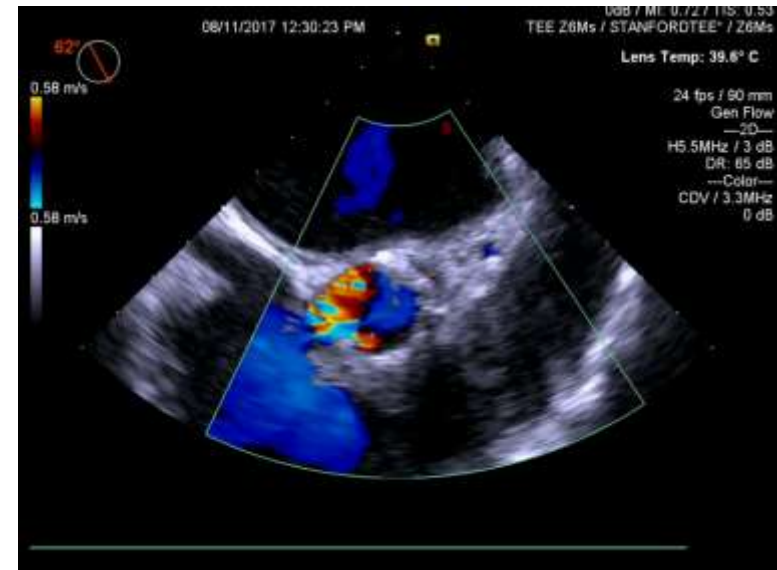
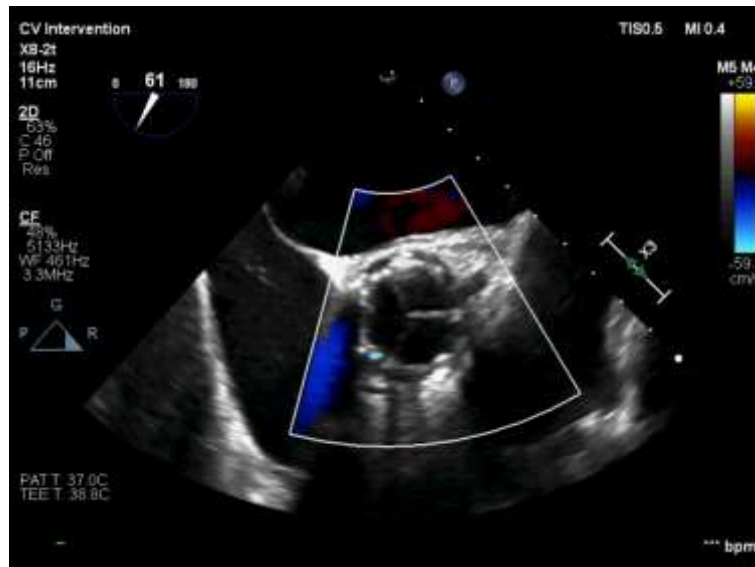
## 2017 Year to Date:

| Description              | January | February | March | Total |
|--------------------------|---------|----------|-------|-------|
| Number of Cases          | 19      | 22       | 19    | 60    |
| Average PPLOS            | 3       | 3        | 2     | 2.73  |
| No. ICU Pts              | 4       | 3        | 5     | 12    |
| Average ICU Pt PPLOS     | 6       | 3        | 2.8   | 4.8   |
| No. Non-ICU Pts          | 15      | 19       | 14    | 48    |
| Average Non-ICU Pt PPLOS | 2       | 2        | 2     | 2     |

- 80% Fast Track
- PPLOS down from 3 to 2.73
- No patients has any PVL more than mild at the end of the procedure



# Three iTAVR last Friday.....(4 on Tuesday)

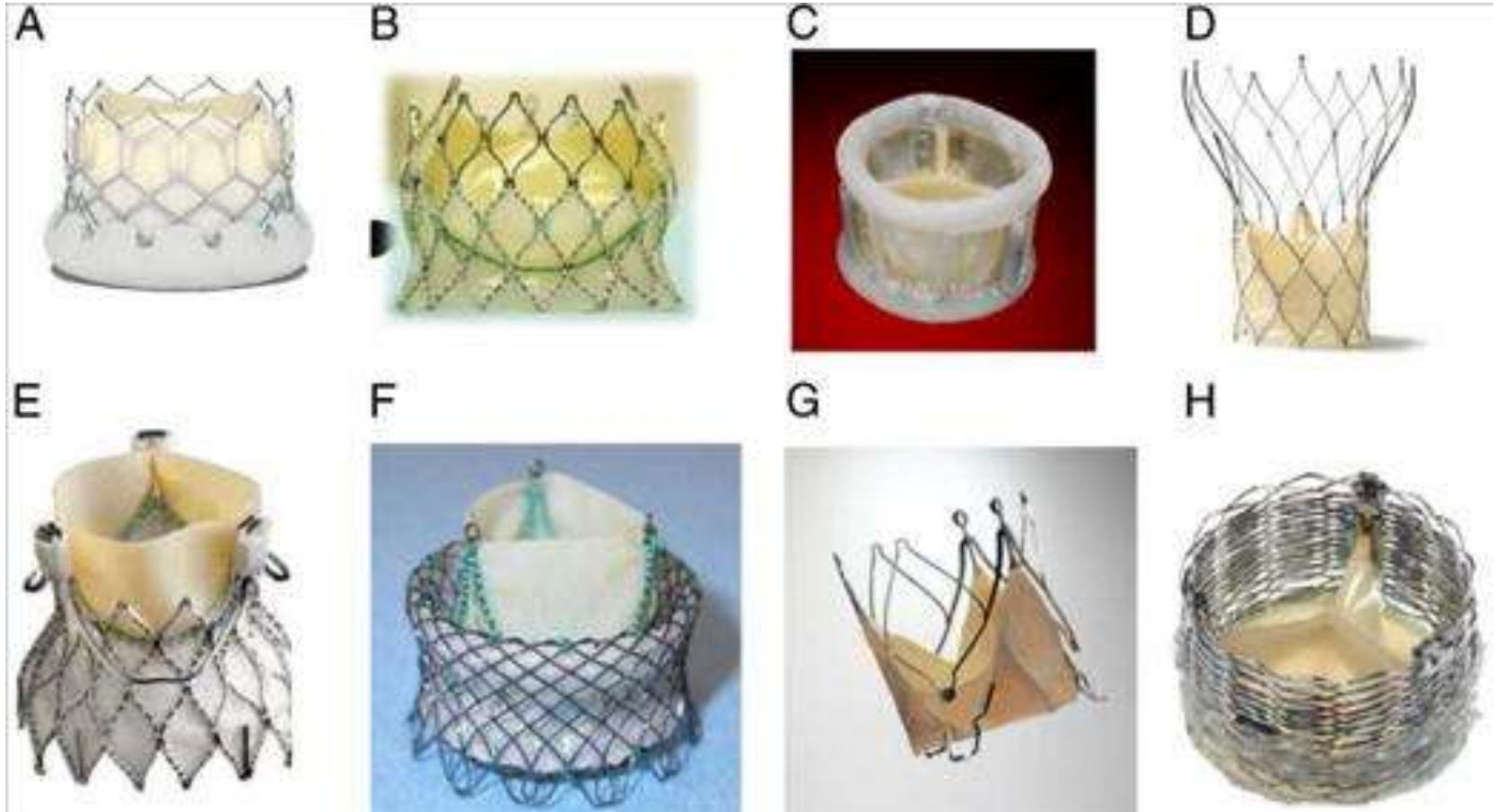


All none or trace PVL  
(one inflation) !





# ***New Generations of Transcatheter Heart Valves to Prevent PVR***

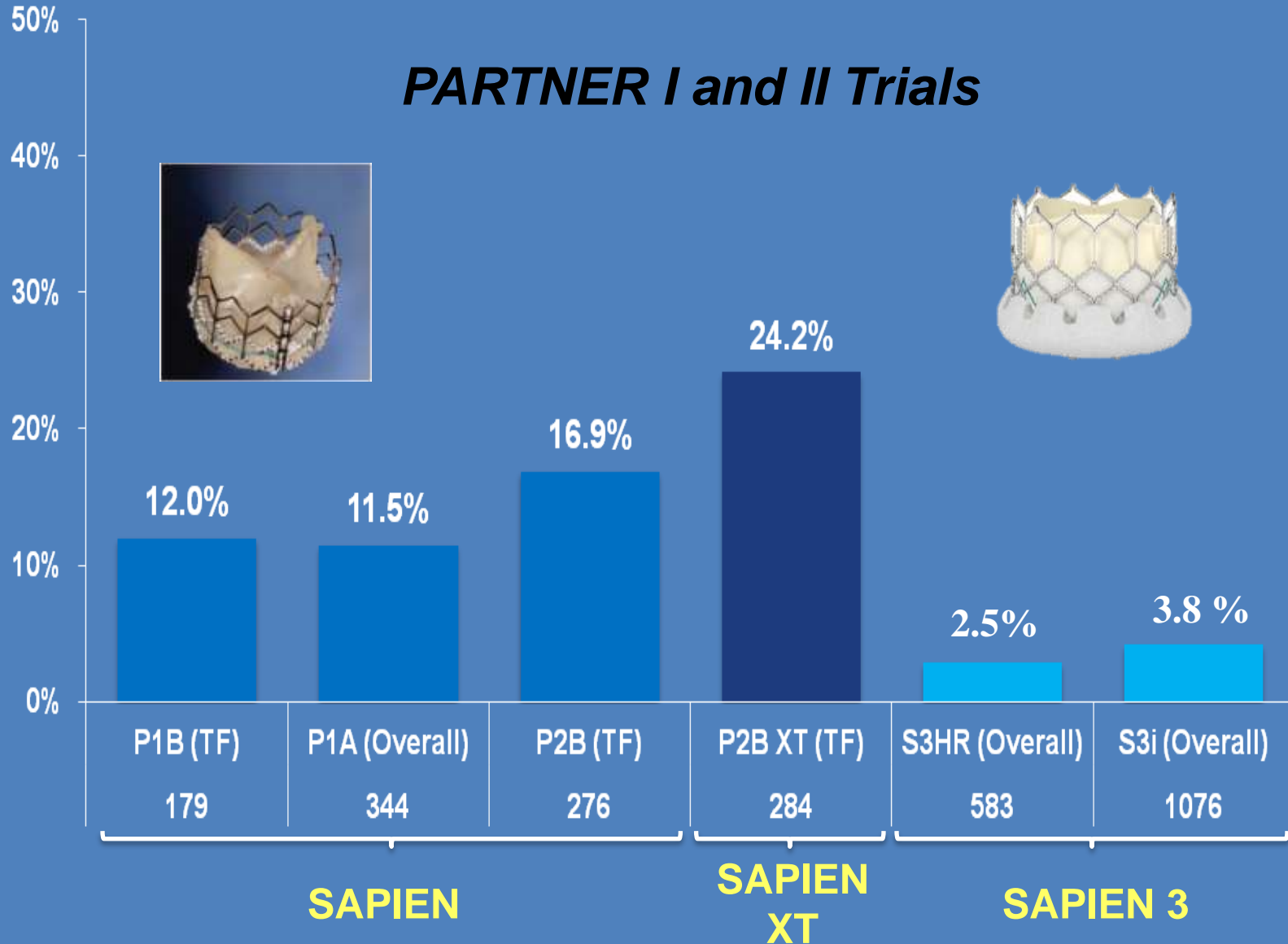




# Moderate/Severe PVR at 30 Days

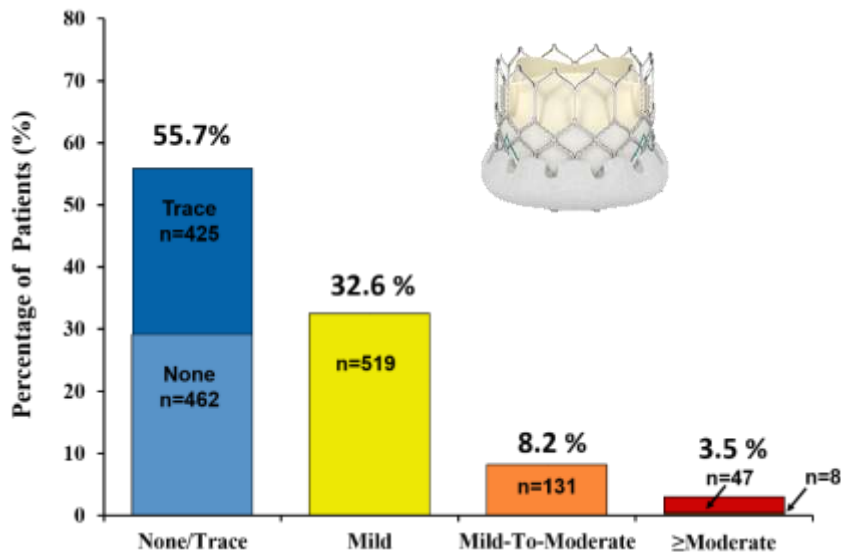
## Edwards SAPIEN Valves

### ***PARTNER I and II Trials***



# Prevalence of Paravalvular Regurgitation with New Generations of THVs

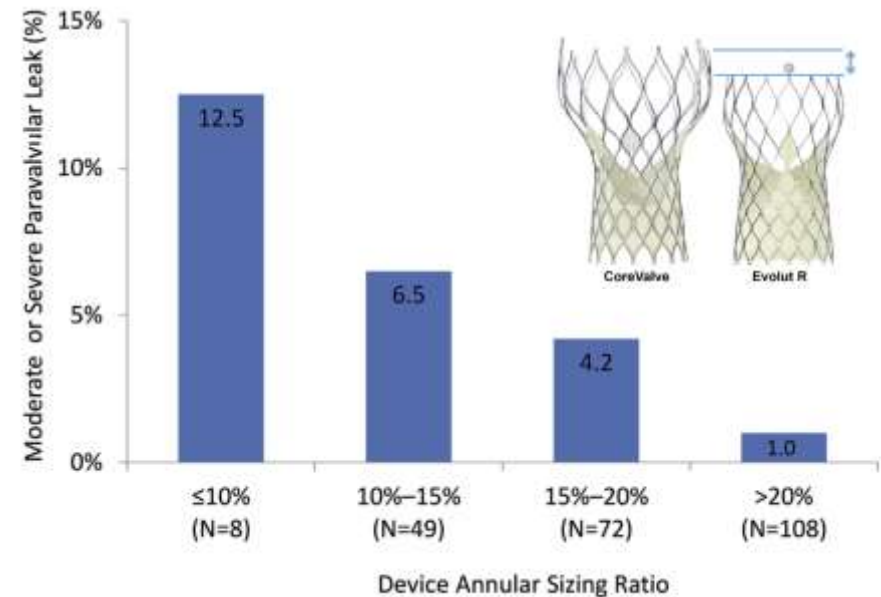
## PARTNER 2 – SAPIEN 3 Registry



**3.5 %  $\geq$  Moderate PVR**  
**40.8% Mild PVR**

*Pibarot et al. TCT 2016*

## EVOLUT R US Study



**5.7 %  $\geq$  Moderate PVR**  
**32.6 % Mild PVR**

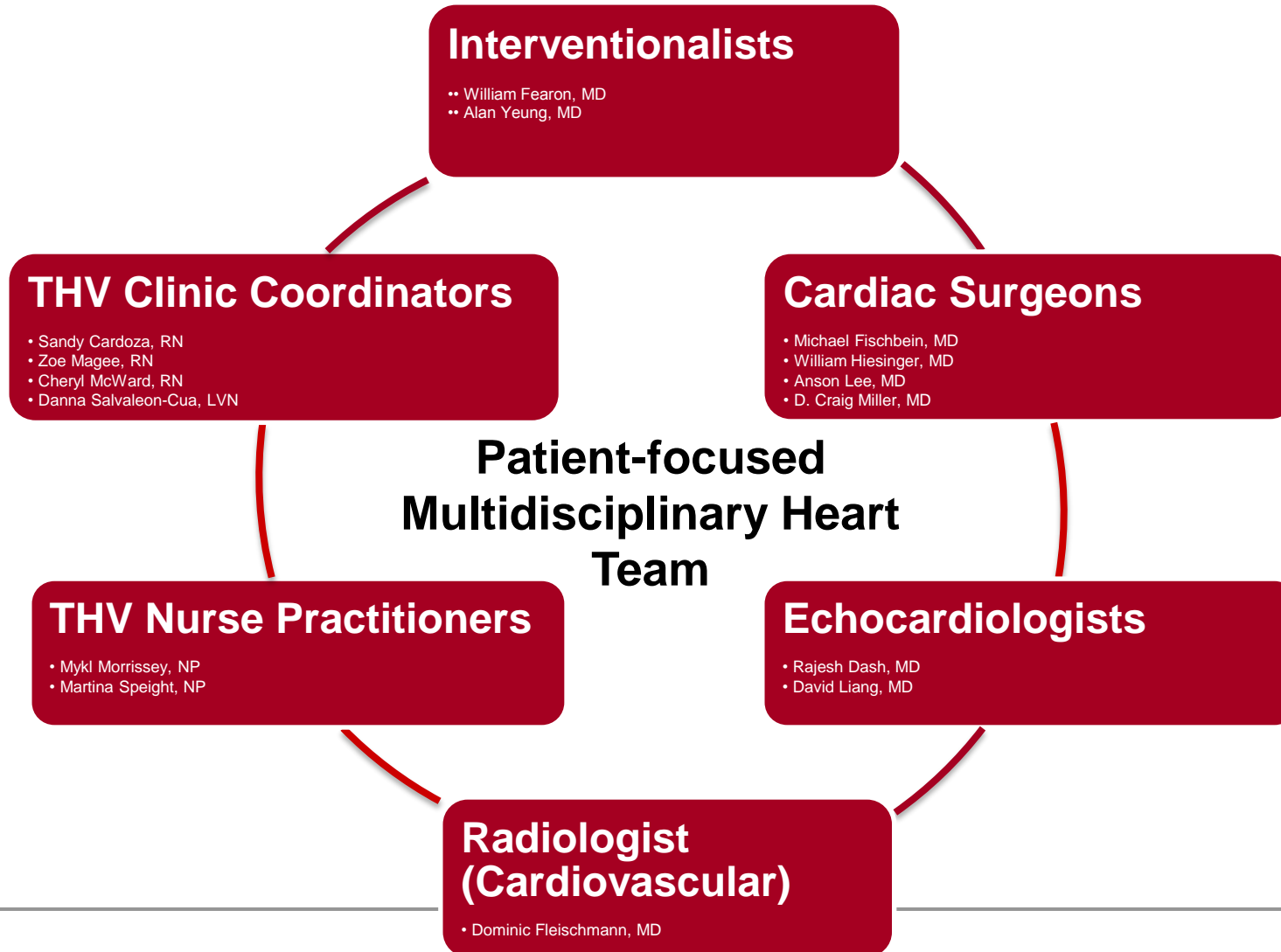
*Popma, JACC Int 2017; 10: 268-275*

# Sizing Strategy and PVL Prevention

- Accurate Sizing: CT
- Upsizing or downsizing
- Intraoperative TEE Verification & Monitoring
- No predilation
- One inflation strategy
- Know the imperfect anatomy



# Stanford Heart Team



MRN 0892502-6

Proposed Treatment 8/14/2017

Referring MD: ACY

THV MDs: ACY/AL

RN: CM

**History:** 86 year old male with history of HTN, HLD, AF, CKD, CAD, prostate CA, and severe symptomatic AS. s/p CABG x 4 (LIMA to LAD, SVG to D1, OM1, rPDA) in 1988. s/p PCI/DES of SVG to OM1 and PPM (Medtronic) implant in June 2016. Currently symptomatic of increased angina

|                                  |      |               |               |               |              |     |  |
|----------------------------------|------|---------------|---------------|---------------|--------------|-----|--|
| PFTs:                            | FEV1 | 1.9 L (104%)  | Frailty:      | BMI           | 27.1         | STS | 7.9%   |
|                                  | DLCO | 11.6 mL (56%) |               | Serum Albumin | 3.6 g/dL (-) |     | 86 year old, male, Caucasian, 69.6 kg, 161.0 m (BSA 1.76), Cr 1.35, HTN, s/p PCI (remote), s/p CABG, NYHA Class II, 3v CAD, EF 48%, AS, MS, trace AI, moderate MR, trace TR, first re-op, elective |
| Anticoagulation History/Regimen: |      |               | Grip Strength | ADLs          | 6/6 (-)      |     |  |
| ASA and Plavix                   |      |               |               | 5m WT         | 20 kg (+)    |     |  |
|                                  |      |               | Score         | 4.38 (-)      |              |     |  |
|                                  |      |               |               | 1/4           |              |     |  |

|       |          |               |          |        |               |                   |         |           |                        |            |                     |
|-------|----------|---------------|----------|--------|---------------|-------------------|---------|-----------|------------------------|------------|---------------------|
| Echo: | Date     | 8/4/2017      | RHC:     | RA     | -             | Coronary heights: | LCA     | 19.5 mm   | SOV Diameters:         | RCC        | 35.0 mm             |
|       | AVA      | 0.67 cm2      |          | RV     | -             |                   | RCA     | 22 mm     |                        | LCC        | 35.8 mm             |
| -     | AVA1     | 0.38 cm2/m2   | Cors:    | PA     | -             | Vascular access:  | RCIA    | 8.8 x 6.9 | SOV heights > 15 mm:   | NCC        | 36.2 mm             |
|       | V2 Max   | 3.9 m/sec     |          | PCW    | -             |                   | REIA #1 | 7.0 x 5.1 |                        | Yes        |                     |
|       | Gradient | 40 mmHg       | 08/03/16 | CO     | -             | (in mm)           | REIA #2 | 7.2 x 6.7 | Ascending Ao diameter: | Long Axis  | 31.4 mm             |
|       | V1/V2    | -             |          | CI     | -             |                   | RCFA    | 7.5 x 7.3 |                        | Short Axis | 29.8 mm             |
|       | EF       | 48%           |          | LAD    | 90% distal    |                   | LCIA    | 8.4 x 8.1 | Annulus:               | Diameter   | ~27.0 mm            |
|       | RVSP     | 30 mmHg       |          | LAD    | 100% ostial   |                   | LEIA #1 | 8.0 x 7.9 |                        | Long Axis  | 29.4 mm             |
|       | AI       | Trace         |          | LCX    | 100% proximal |                   | LEIA #2 | 9.0 x 8.2 |                        | Short Axis | 24.2 mm             |
|       | MR       | Mild-moderate |          | RCA    | 100%          |                   | LCFA    | 8.6 x 8.5 |                        | Area       | 584 mm <sup>2</sup> |
|       | TR       | Trace         |          | Grafts | See Notes     |                   |         |           |                        | Perimeter  | 86.6 mm             |

**Notes:** Echo: Mild MS with mean gradient of 4 mmHg. Cath: patent LIMA to LAD and SVG to OM1, CTO of SVG to D1 and rPDA.

|  |   |
|--|---|
| <b>Summary:</b>  | <b>THV Notes:</b>   |
| <ul style="list-style-type: none"> <li>• 86 year old male</li> <li>• STS 7.9%</li> <li>• High Risk</li> <li>•</li> </ul> | <ul style="list-style-type: none"> <li>• #</li> <li>• 29 mm Sapien 3</li> <li>• Transfemoral approach - Left side</li> <li>• Fast track eligible</li> </ul> |
|  | <ul style="list-style-type: none"> <li>• Check cors/grfts at time of TAVR</li> <li>•</li> </ul>   |

# Sizing Strategy and PVL Prevention

- Accurate Sizing: CT
- Upsizing or downsizing
- Intraoperative TEE Verification & Monitoring
- No predilation
- One inflation strategy
- Know the imperfect anatomy

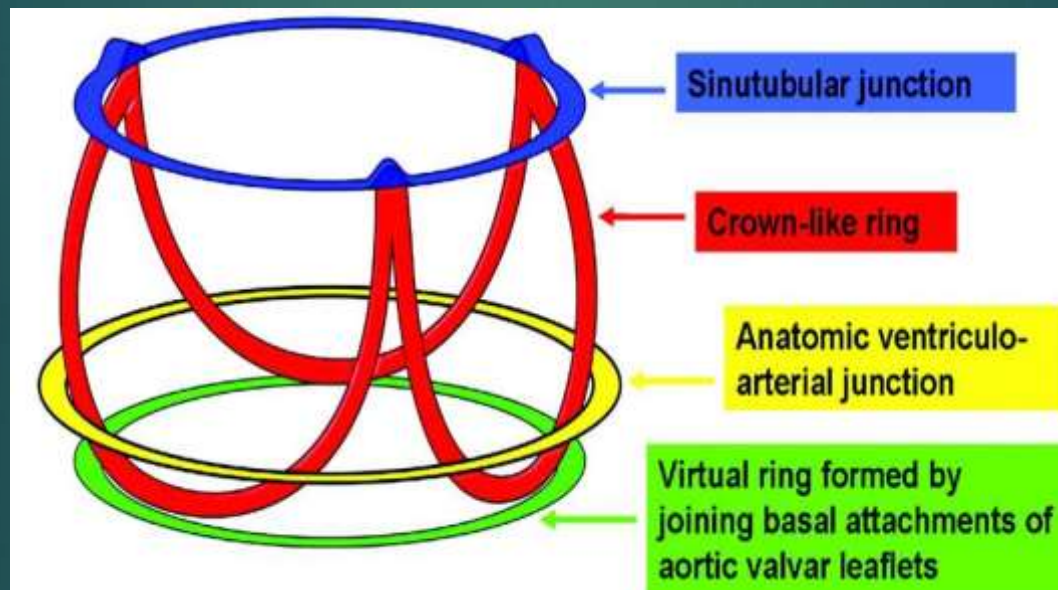


# Why do we need these aortic measurements?

- ▶ Predictors of paravalvular leak, BE/SE: undersizing, calcification, implant depth
  - Athappan et al, JACC 2013
- ▶ Predictors of root rupture BE: oversizing > 20%, LVOT calcification
  - Barbanti et al, Circ 2013
- ▶ Predictors of LM occlusion BE/SE: SOV < 30 mm + LMCA distance < 12 mm
  - Ribeiro et al, JACC 2013



# “Virtual” Aortic Annulus – where the transcatheter valve anchors



Piazza N et al. Circ Cardiovasc Interv  
2008;1:74-81

# S3

## EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE

| Annulus Sizing                 |                       | 20 mm                     | 23 mm                     | 26 mm                     | 29 mm                     |
|--------------------------------|-----------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| Native Valve Annulus Size (CT) | Area                  | 273 - 345 mm <sup>2</sup> | 338 - 430 mm <sup>2</sup> | 430 - 546 mm <sup>2</sup> | 540 - 683 mm <sup>2</sup> |
|                                | Area Derived Diameter | 18.6 - 21 mm              | 20.7 - 23.4 mm            | 23.4 - 26.4 mm            | 26.2 - 29.5 mm            |
| Native Valve Annulus Size TEE  |                       | 16 - 19 mm                | 18 - 22 mm                | 21 - 25 mm                | 24 - 28 mm                |

# Corevalve/Evolut

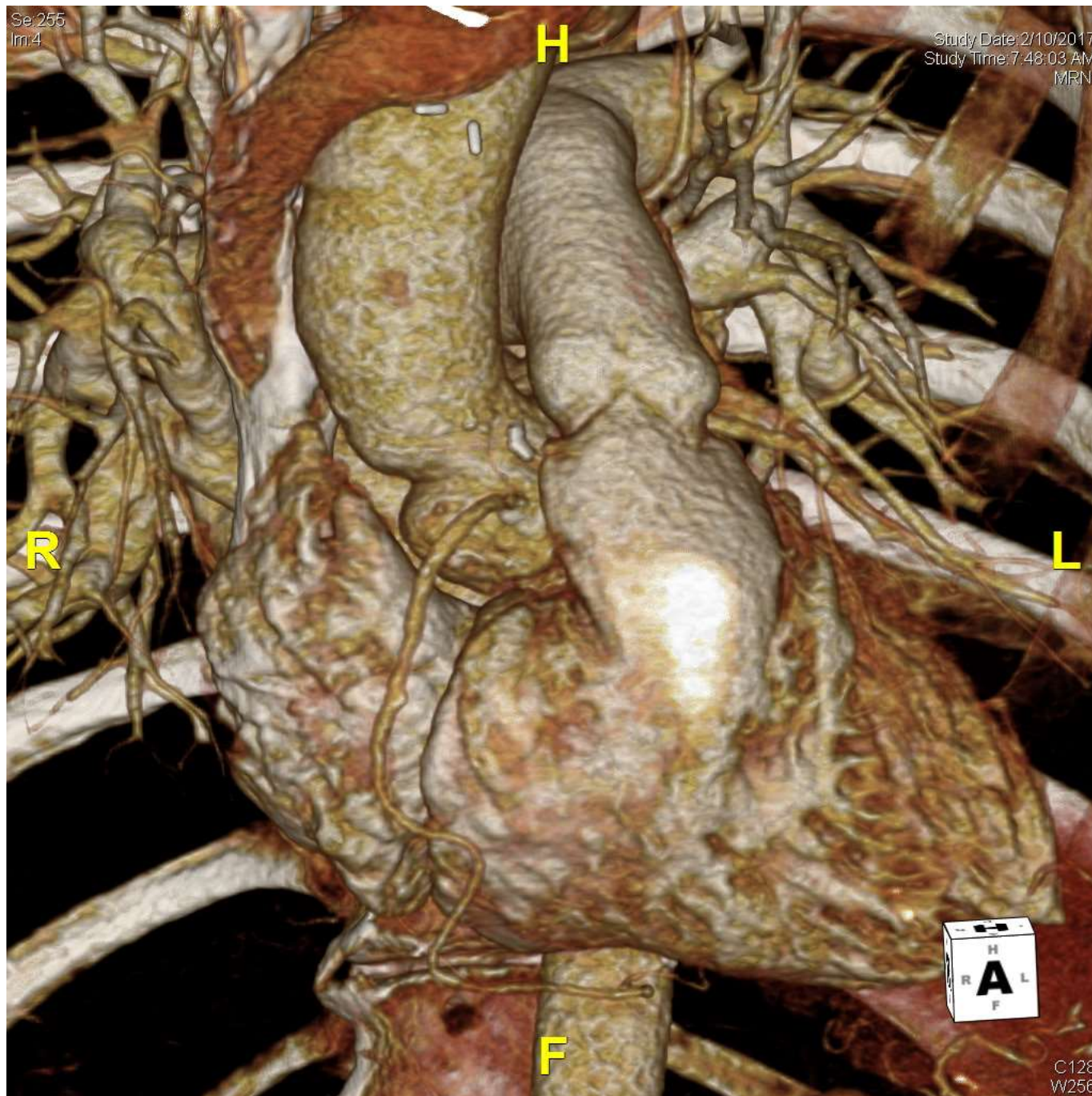
## Device and Patient Selection Measurements per MSCT

| Valve Size | Aortic Annulus Measurements |                   |                | Sinus of Valsalva Diameter | Native Leaflet to Sinutubular Junction Length | Ascending Aorta Diameter* |
|------------|-----------------------------|-------------------|----------------|----------------------------|---|---------------------------|
|            | Diameter                    | Perimeter         | Area Range     |                            |   |                           |
| 23         | 18 mm – 20 mm               | 56.5 mm – 62.8 mm | 254.5-314.2 mm | ≥ 25 mm                    | ≥ 15mm  | ≤ 34 mm                   |
| 26         | 20 mm – 23 mm               | 62.8 mm – 72.3 mm | 314.2-415.5 mm | ≥ 27 mm                    | ≥ 15mm  | ≤ 40 mm                   |
| 29         | 23 mm – 27 mm               | 72.3 mm – 84.8 mm | 415.5-572.6 mm | ≥ 29 mm                    | ≥ 15mm  | ≤ 43 mm                   |
| 31         | 26 mm – 29 mm               | 81.6 mm – 91.1 mm | 530.9-660.5 mm | ≥ 29 mm                    | ≥ 15mm  | ≤ 43 mm                   |

\*Ascending Aorta measurements are taken at 30 mm from the aortic annulus for the 23 mm device and at 40 mm from the aortic annulus for the 26, 29, and 31 mm devices.

Se:255  
Im:4

Study Date: 2/10/2017  
Study Time: 7:48:03 AM  
MRN:



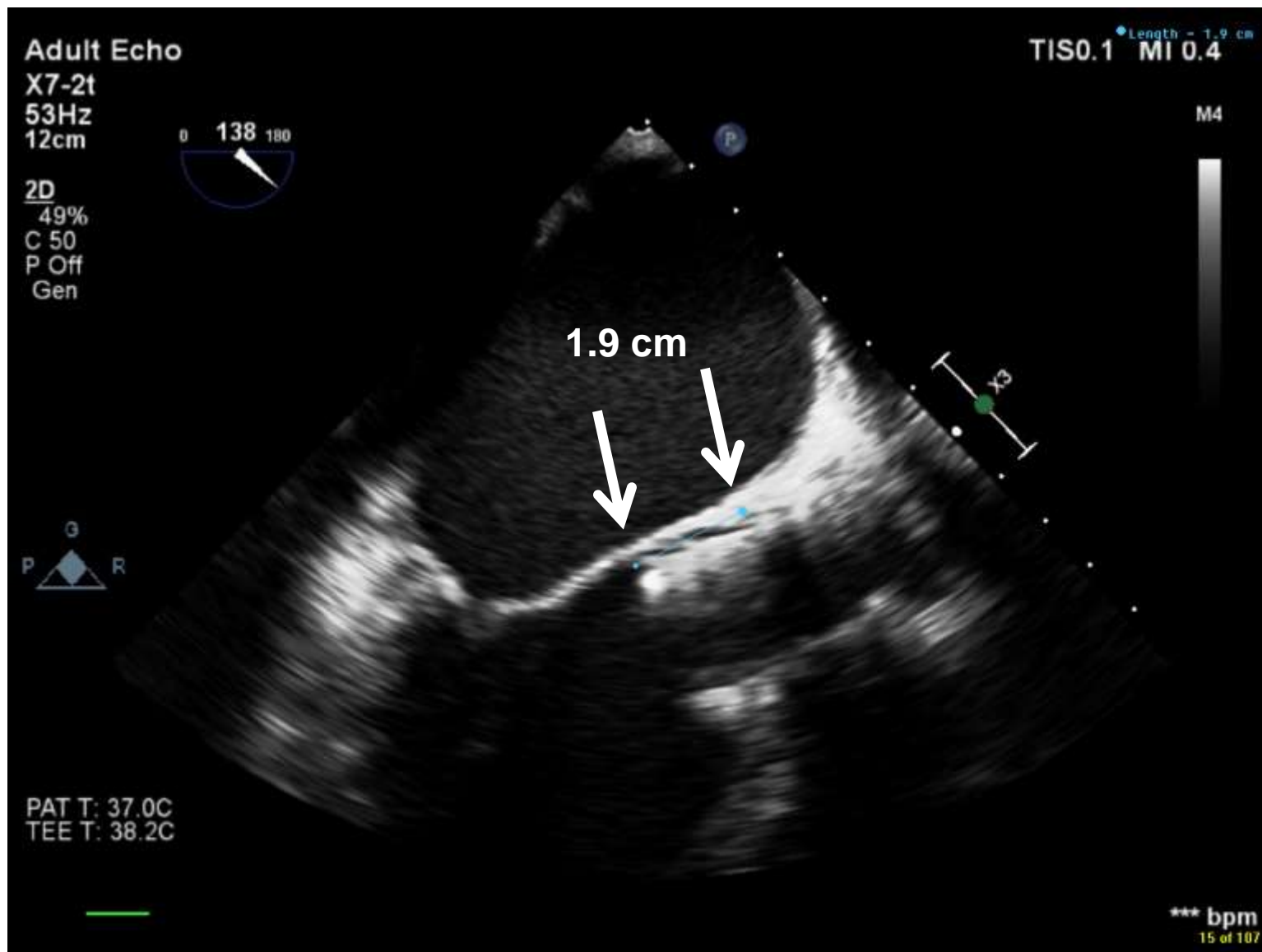
C128  
W256





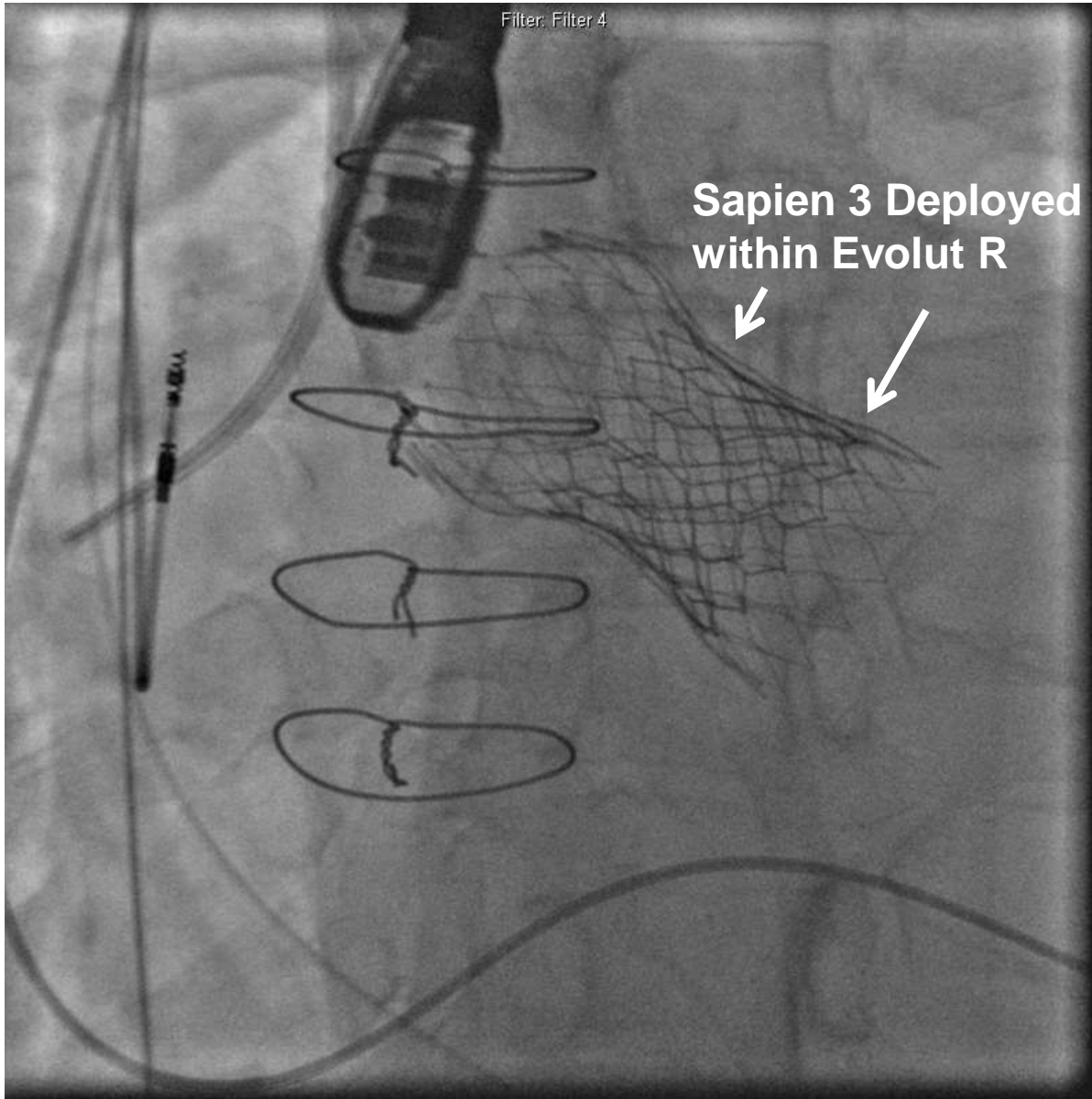
# Ascending Aorta





Filter: Filter 4

**Sapien 3 Deployed  
within Evolut R**





# Sizing Strategy and PVL Prevention

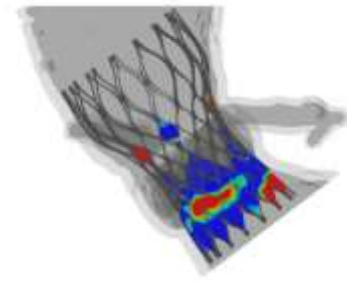
- Accurate Sizing: CT
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# *Evolution of TAVR in 2017*

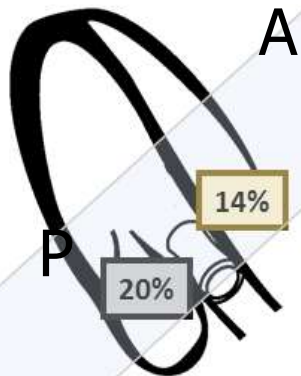
- **Less and less invasive TAVR: majority of cases performed under conscious sedation ( $\geq 70\%$ ) with transfemoral approach ( $\geq 90\%$ )**
- **Consequences of this evolution:**
  - **Less and less comprehensive imaging:**
    - **No TEE**
    - **Ventriculography only**
    - **Suboptimal TTE**
  - **Risk of underdetection of PVR at the time of procedure**

# Low sensitivity to detect jets in certain locations (posterior jets)



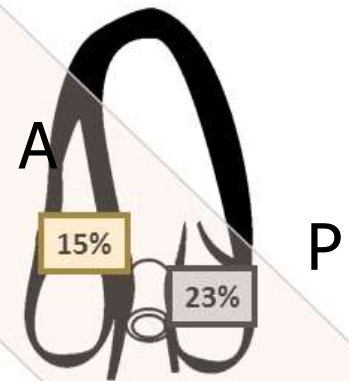
Apical three chamber view

A3C View

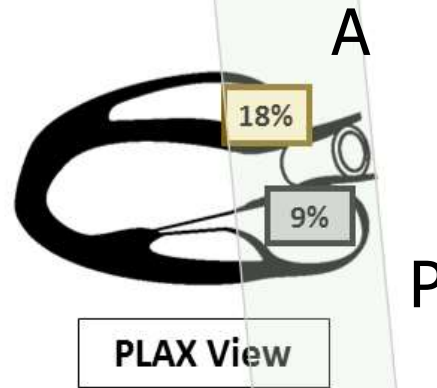


Parasternal short axis view

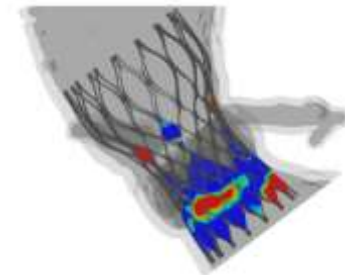
Apical five chamber view



Parasternal long axis view

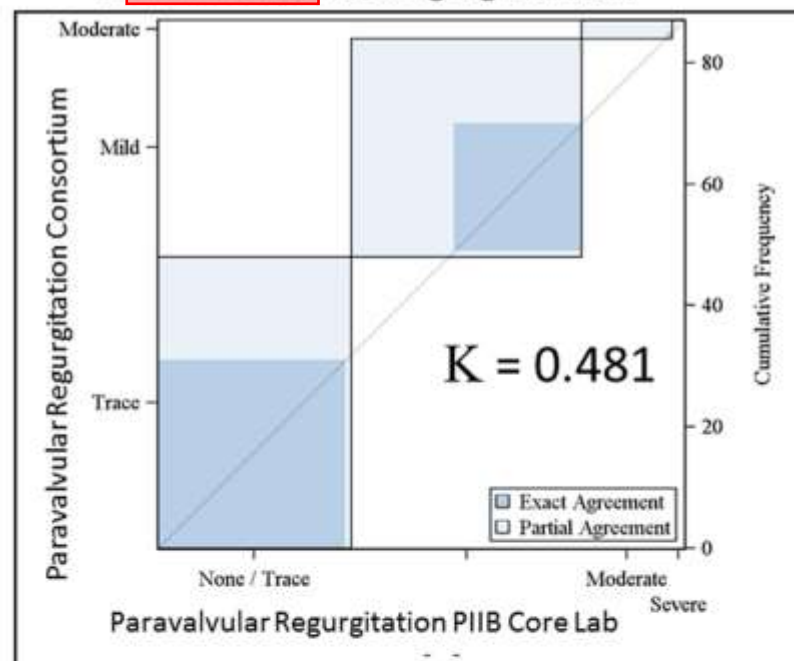


# Assessment of Paravalvular Aortic Regurgitation after Transcatheter Aortic Valve Replacement: Intra-Core Laboratory Variability



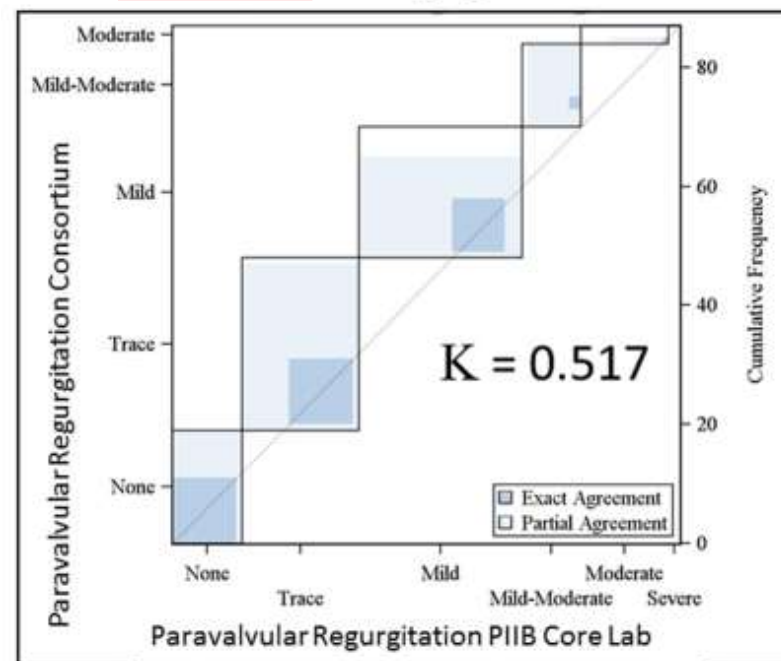
Rebecca T. Hahn, MD, FACC, Philippe Pibarot, DVM, PhD, FACC, Neil J. Weissman, MD, FACC, Leonardo Rodriguez, MD, FACC, and Wael A. Jaber, MD, FACC, *New York, New York; Québec City, Québec, Canada; Washington, District of Columbia; and Cleveland, Ohio*

**A. PVR 4-class Grading Agreement**



None, Trace / Mild / Moderate/ Severe

**B. PVR 7-class Grading Agreement**



None / Trace / Mild /Mild to Moderate /  
Moderate / Moderate to Severe / Severe

# CV Intervention

X8-2t

11Hz

10cm

## xPlane

64%

64%

46dB

P Off

Res

## CF

48%

5999Hz

WF 539Hz

3.3MHz



PAT T: 37.0C  
TEE T: 39.1C

TIS0.5

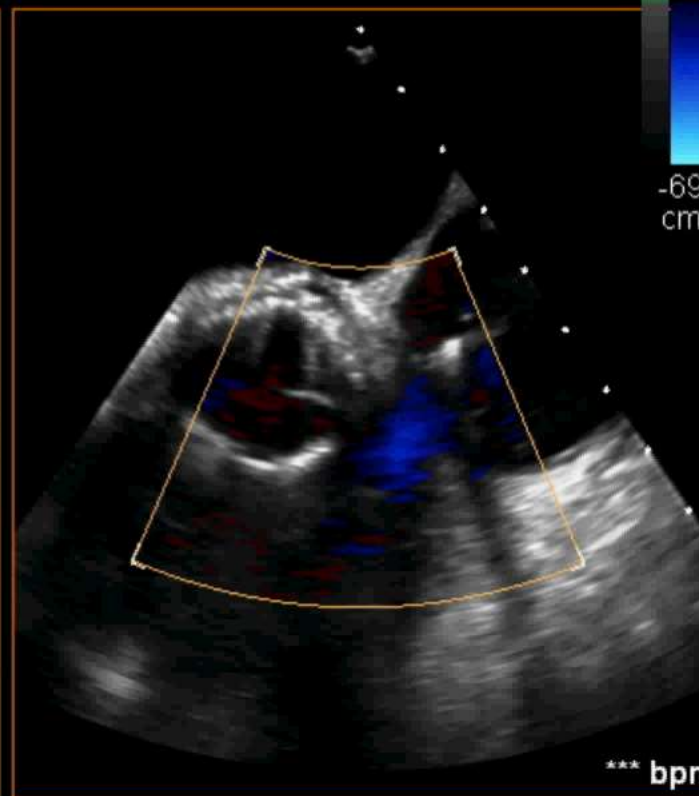
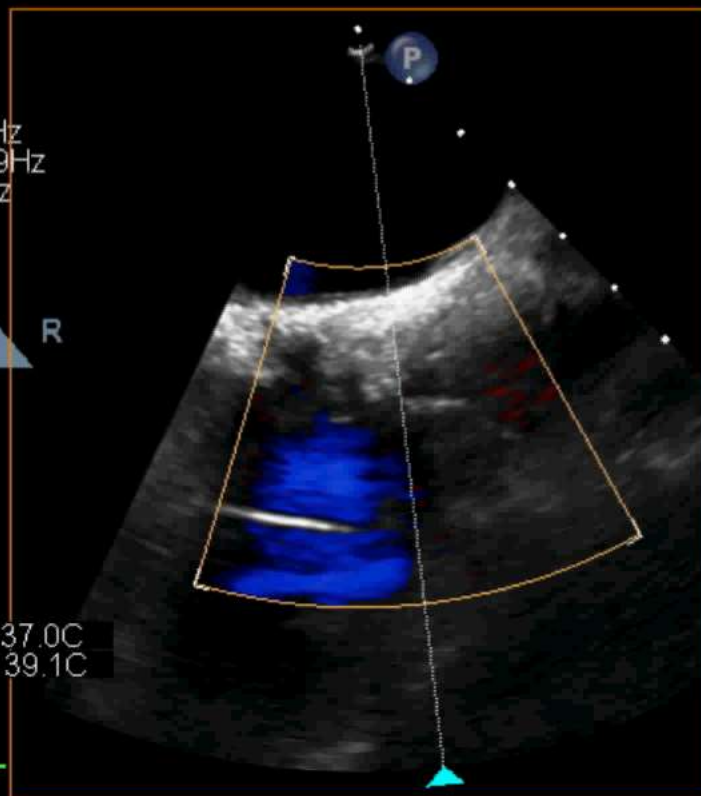
MI 0.4

M5M4

+69.3

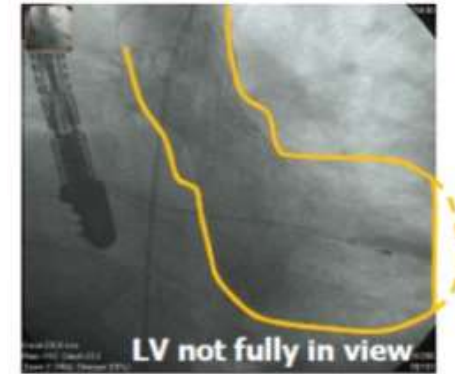
-69.3

cm/s

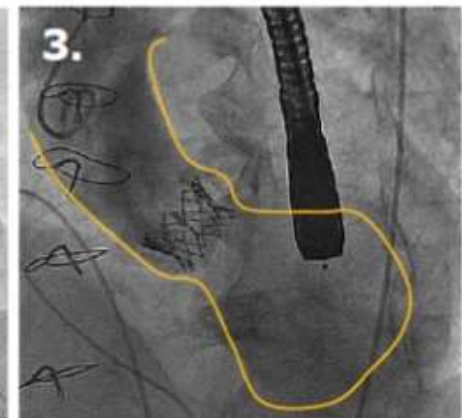
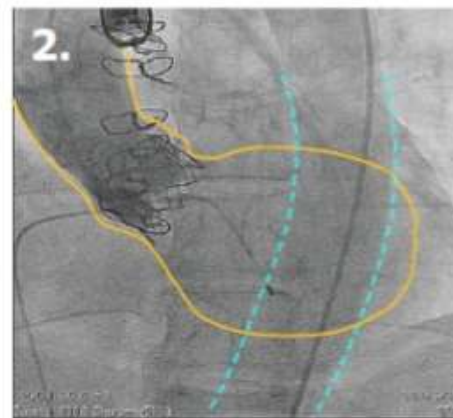
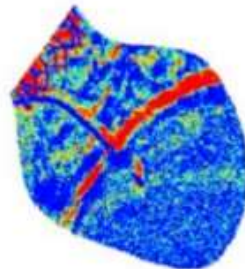
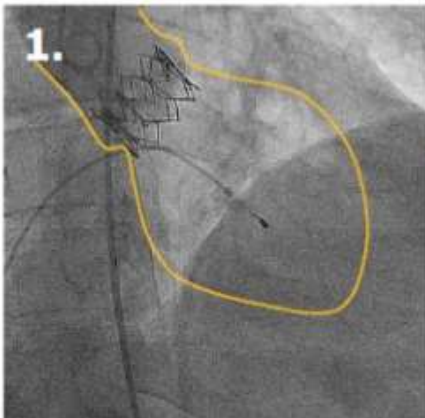


# The interrogation of the entire LV is not always feasible, because of...

- Apex sometimes not visualized



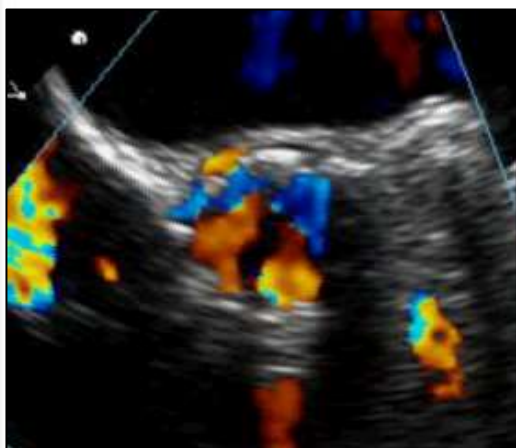
- Video-densitometry can be influenced by a number of back ground structures, such as...
  1. Diaphragm, lung field and gastric or bowel gas
  2. Contrast-filled descending aorta
  3. Dense objects such as TOE probes in the ROI



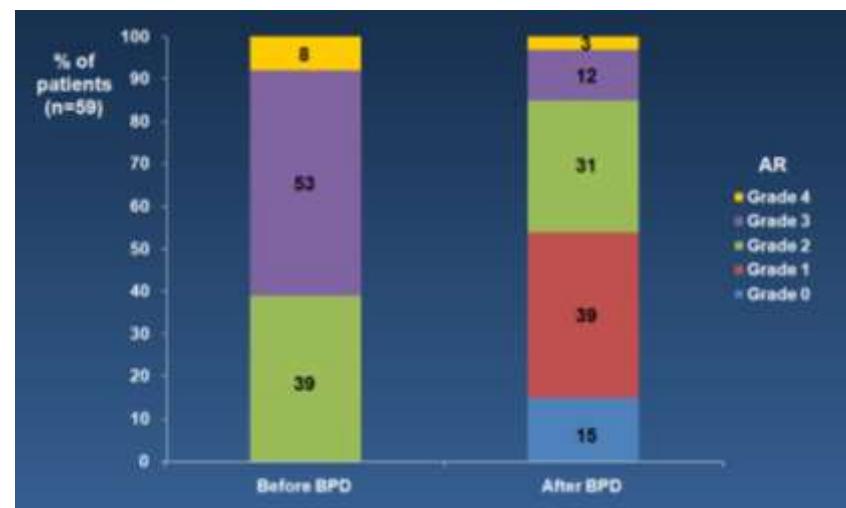
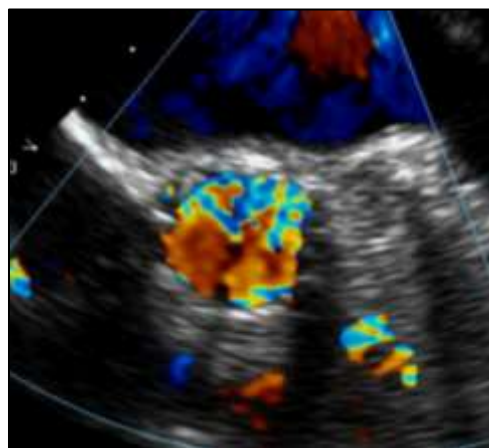


# *Impact of Balloon Post-dilation on PVR And Outcomes*

Pre-BPD



Post-BPD

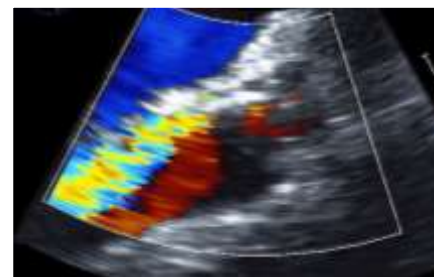
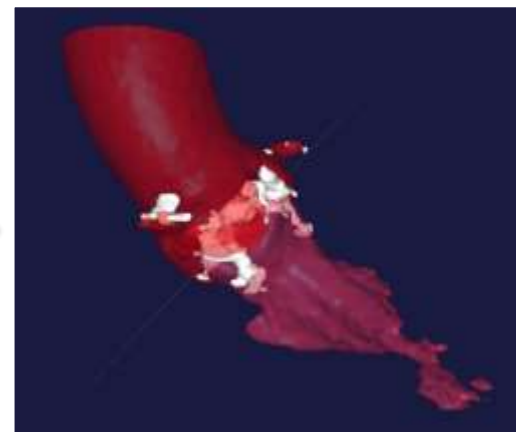
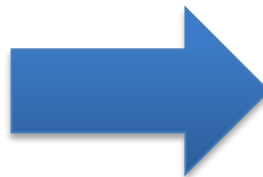
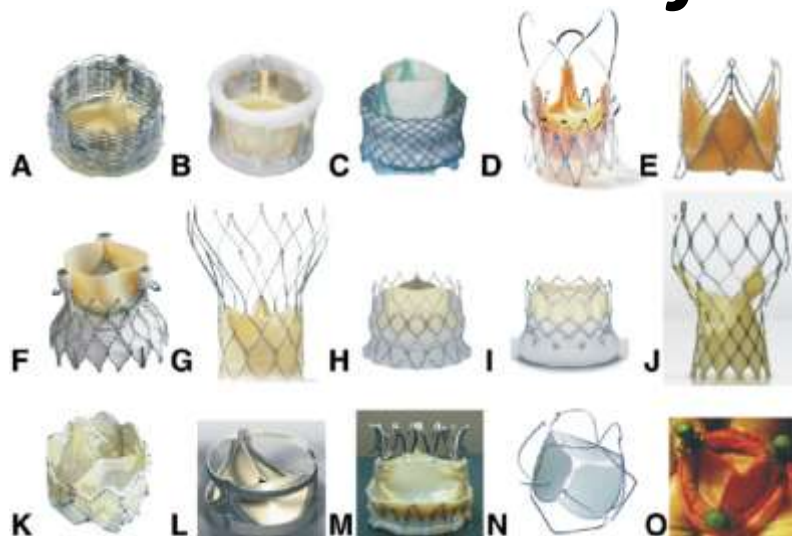


**BPD: 2.5-fold increase in the risk of early cerebrovascular events**



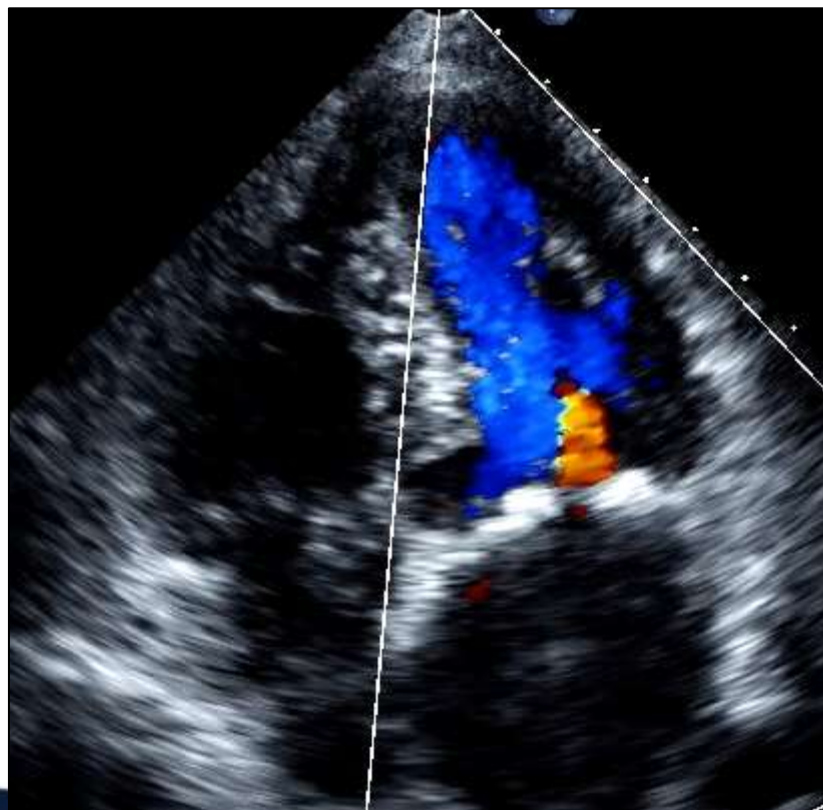
# ***New Generations of THV***

# ***Hostile Anatomy***

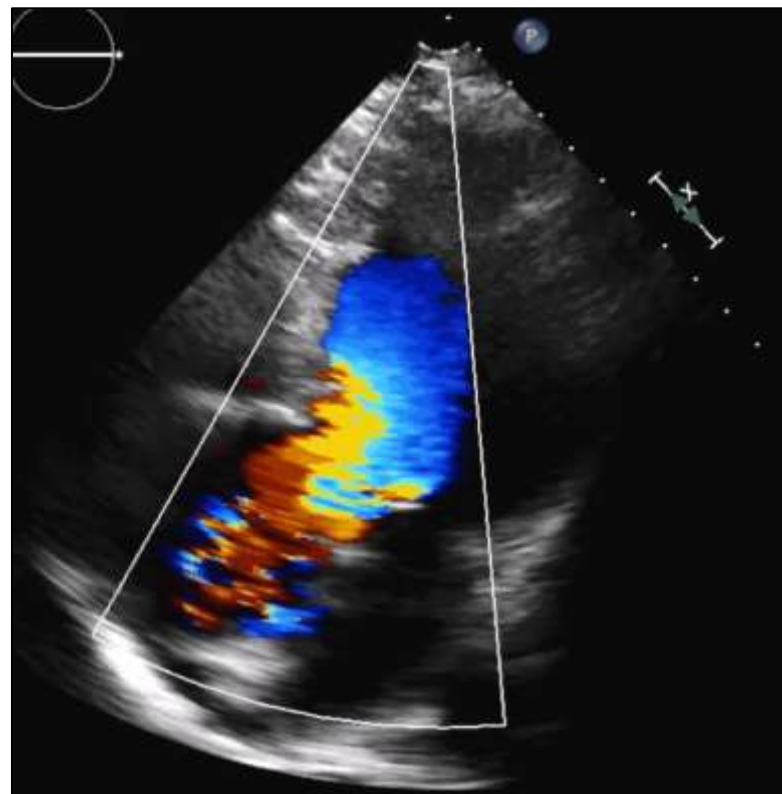


# *The impact of PVR is not equivalent in all patients*

*A mild PVR may be harmful in  
patients with pure AS*

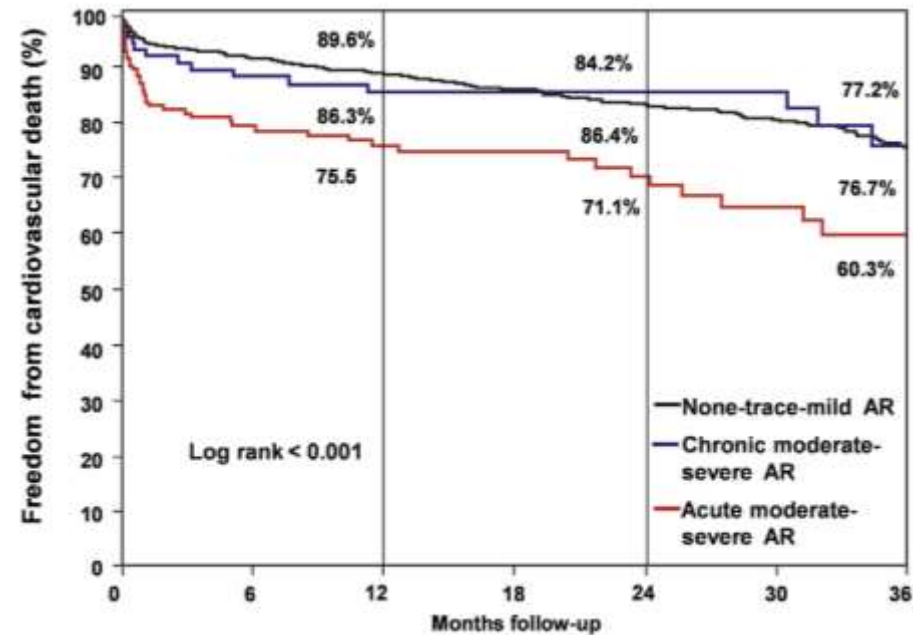
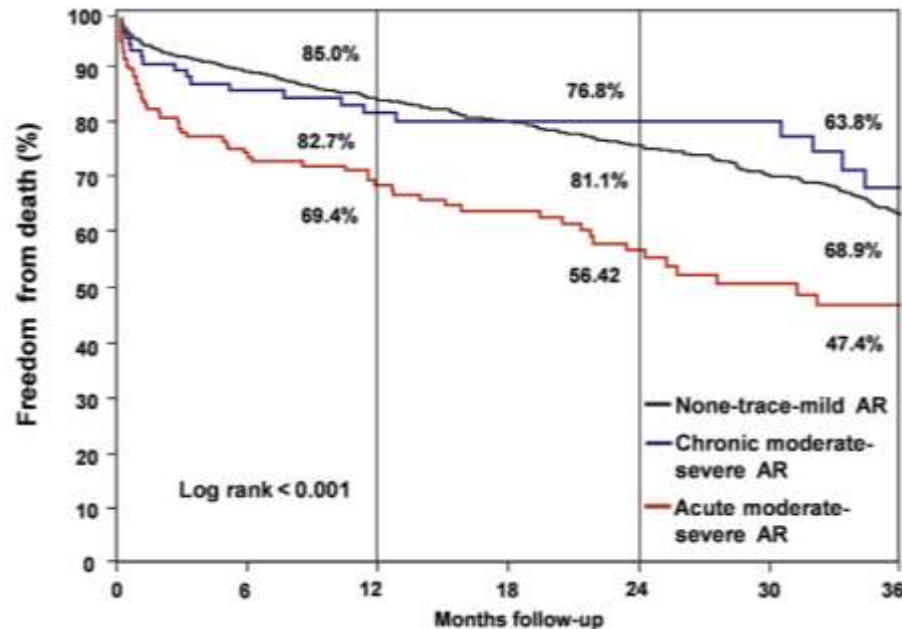


*A moderate PVR may be  
well tolerated by patients  
with pre-existent AR*



# Effect of Acuteness of AR on Mortality After TAVR

## Multicenter Study (1735 Patients)



*Jerez-Valero et al. J Am Coll Cardiol Interv 2014;7:1022–32*

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- No predilation
- One inflation strategy
- Know the imperfect anatomy
- Precise and Reproducible

